

Remarks

Claims 1-15 are pending in the application.

Applicants traverse the §102(e) rejection of claims 1-5 and 7-15 set forth at page 2 of the Office Action. In support of their traversal, Applicants note that Fraser *et al.* (the '023 patent) do not teach a pest gut epithelial cell recognition portion of a protein. Although the Examiner is correct that the '023 patent describes a polyhedrin fusion protein, this point is inapposite. The polyhedrin protein does not comprise an epithelial cell recognition portion, and thus does not act as a targeting protein. Rather, the polyhedrin protein has two roles in viral transmission: (a) to protect embedded virions during transmission between host organisms, and (b) to effect release of the virions at the primary site of infection, the mid-gut epithelium cells, by dissolving in the high-pH (10.5) environment of the mid-gut lumen. Thus it is not a receptor-targeting protein, but instead dissolves away from the viral particles as it passes through the insect mid-gut, thereby releasing them to infect the mid-gut cells. Further, the '023 patent teaches the use of a polyhedrin fusion protein for increased expression of proteins of interest. It is used as a mechanism to express other proteins because it is unnecessary for viral propagation in the lab and becomes the most predominant protein in the cell, often composing 25-50% of the total stainable protein in a cell by 70 hours post infection. See, for example, Miller (1988) "Baculoviruses as gene expression vectors" *Ann. Rev. Microbiol.* 42:177-199, submitted herewith. The contribution of the '023 patent to the art is thus the idea of using the expression characteristics of polyhedrin proteins to produce other proteins of interest at similar levels. Accordingly, not only does the '023 patent fail to teach the "pest gut epithelial cell recognition portion of a protein" specified in the claims, but it fails to provide even a suggestion of using a receptor-targeting protein to deliver toxins. Therefore, the '023 patent fails to anticipate the claims. Reconsideration is respectfully requested.

Next, Applicants traverse the §103(a) rejection of claims 1-15 set forth at page 3 of the Office Action. The primary reference, Pennock *et al.*, teaches vectors comprising the N-terminal region of the polyhedrin gene fused to a β-galactosidase gene for expression in insect cells. Again, as discussed above in connection with the '023 patent, the polyhedrin protein is not a receptor-targeting protein, and does not have a pest gut epithelial cell recognition portion as required by the claims. Pennock *et al.* is concerned with expression of high levels of proteins of interest, and thus uses the expressability characteristics of polyhedrin protein to achieve this goal. There is no suggestion to use

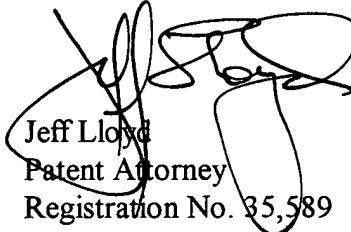
a receptor-targeting portion of a protein to deliver toxins to a specific target site. The secondary references fail to cure this deficiency. They are merely an aggregation of publications which disclose various toxins, but without the crucial teaching that would suggest using a receptor-targeting portion of a protein to deliver a toxin to a specific target site. Without such a teaching, there is no motivation to combine the references as is attempted in the Office Action. To support an obviousness rejection, one must find both the suggestion of the combination and the expectation of success in the prior art. See *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). In this case one finds neither. The only motivation to combine the references in the manner depicted in the Office Action is provided by the teachings of the subject application itself. Such hindsight reconstruction is insufficient to support an obviousness rejection. Since no *prima facie* case of obviousness has been set forth, Applicants respectfully request reconsideration and withdrawal of this rejection.

In view of the foregoing, Applicants believe that all claims as currently pending are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge to Deposit Account 19-0065 any fees under 37 CFR 1.16 or 1.17 as required by this paper.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this amendment, or if the Examiner believes that a telephone interview would expedite prosecution of the subject application to completion.

Respectfully submitted,



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